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(54) **Suture fasteners**

Gerät zur Befestigung von Nahtmaterial

Fermetures pour sutures

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## Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

**[0001]** The present invention relates generally to a suture fastener. Particularly, the present invention is related to suture fasteners for holding one or more suture strands in a configuration so as to fasten.

**[0002]** Sutures are typically used to hold tissue in desired positions, such as to close wounds or to correct malformations. The suture lines are threaded through the tissue any number of times and held in place to maintain the new tissue configuration. In order to hold the suture taught over an extended period of time, a knot is commonly formed in the suture ends. Suturing is often thought of as an art form learned over an extended period of time. There are many types of sutures and knots, each providing certain advantages in a particular operative setting. At least as complicated as the suturing itself is the knot-tying which must occur to secure each of the sutures. Where individual sutures are placed to close a long wound, an individual knot is tied in each place.

**[0003]** Knots differ considerably in their configuration, function, complexity and characteristics. By way of example, it will be noted that knots typically involve several throws of the sutures ends relative to each other. In one common knot, three half-hitches are used with the first half-hitch having four throws and each subsequent half-hitch having three throws. In this case, tying of a single knot to close a single suture involves ten throws. The simplest knots may be easier to tie, but in distant locations even the simple knots can be complicated where it is difficult to achieve proximity to the suture site. In these locations, more complicated slip knots have been used. These knots can be tied at a remote location and then slipped down to the surgical site. Except for a few extremely complex knots, slip knots have the undesirable tendency to slip in both directions. As a result, their ease of tying and movement to the surgical site is offset by their tendency to lose their grip at the suture site.

**[0004]** From these few examples, it can be appreciated that knots, as a suture-fastening system, are time-consuming, difficult to tie, hard to place, often unreliable as a holding system, difficult to adjust and impossible to relocate. This is particularly the case in the context of percutaneous, endovascular, laparoscopic, minimally invasive or robotic procedures. For these reasons, it would be desirable to provide alternative methods, systems, and kits for fastening sutures or similar devices which overcome at least some of the shortcomings noted above.

2. Description of the Background Art

**[0005]** Hart et al., U.S. Patent No. 6,099,553, describes a suture system for closing a wound. The suture system includes a securing mechanism having a plurality of tines wherein the mechanism has a first position for capturing suture ends and a second position for permanently holding the suture ends in a fixed relationship. In a third position, the securing mechanism frictionally engages the suture ends in a sliding relationship.

**[0006]** Batra, U.S. Patent No. 4,510,934, describes a surgical suture which consists of a monofilament core and a braided sheath surrounding the core. The core is later removed whereupon the sheath becomes flexible for tying into a secure knot.

**[0007]** WO01/66001 is the closest prior art and describes suture clips and delivery devices and methods. Figures 18 to 34 of WO01/6601 show suture clips with alignable finger systems that capture a suture when placed in an unlined condition. WO00/02489 describes a fusible collar for securing sutures without knots, and for securing living tissular structures together without sutures. The fusible collar is made of compressible material, and is formed generally in a "c" shape which can be compressed into an "o" shape, with portions of the collar overlapping around the structures to be secured. Energy is applied to the overlapping portions of the collar to cause localized heating and plastic flow so as to fuse the overlapped portions together. The collar can include one or more energy directors on a contact surface to direct, and focus energy to particular regions so as to effect collect to suture welding. WO96/22735 describes apparatus and methods for suturing and ligating anatomical tissue which utilizes one or more knotting elements connected between two or more length portions of filamentous suture material to form one or more contractible loops for confining segments of the length portions therein. The knotting elements receive the suture material to effect a knot for one or more adjustably tensioned stitches created when the segments are passed through the loop and the suture material is received by the knotting elements. WO01/28455 describes methods and devices for improving cardiac functions in hearts having zones of infracted and aneurysmal tissue regions. The described methods and related devices include splinting of the chamber wall proximal the infracted region and devices and methods including suture and patch techniques. WO97/25927 describes a knotting element for use in surgical procedures to effect a knot in a length of filamentous material includes a body for being attached to a segment of the filamentous material and having opposed legs, an engaging member carried by one of the legs and a recess formed in the other of the legs corresponding to the engaging member. The body is movable from an open position wherein the engaging member is disposed externally of the recess to receive a second segment of the filamentous material to a closed position wherein the engaging member is disposed within the recess to immovably fixate the second segment of filamentous material to the knotting element to effect a knot. US4,235,238 describes a coeliac tissue-suturing apparatus comprising a flexible tubular member.

BRIEF SUMMARY OF THE INVENTION

**[0008]** Aspects of the present invention are set out in the appended claims.

**[0009]** There are described herein apparatuses, systems, methods and kits for fastening sutures or similar devices used in medical surgical procedures, in particular, suitable for use with minimally invasive procedures in which sutures are placed with catheter-based devices wherein the tying of knots is particularly challenging. Described suture fasteners provide for fastening the sutures together in a fixed position at any location along the suture strands. In addition, the fasteners are adjustable to allow repositioning of the fastener after placement to a new desired location along the suture strands. Similarly, such fasteners may be used to hold a single suture strand for various applications.

**[0010]** A described suture fastener for adjustably holding one or more suture strands comprises at least one fastening element comprised of a shape-recovery material or other suitable metal, polymer or combination, wherein the element has a tensioned position for engaging the suture strands while allowing sliding of the element relative to the suture strands and a relaxed shape-recovery position for holding the strands in a fixed position relative to the element or to each other. It may be appreciated that the term "tensioned position" is used to describe a position from which the element converts and assumes the shape-recovery position upon proper activation, such as stimulus or release or force. For example, the element may be placed under tension, compression, extension or any high potential energy state when in the tensioned position. Release of the force holding the element in this state allows the element to assume a relaxed shape-recovery position. Alternatively, the element may be in a tensioned position when no external force is applied but wherein the application of heat or energy transitions the form of the element to a relaxed shape-recovery position. Thus, the term "tensioned position" is not intended to limit the scope of the application to only positions under mechanical tension. In the tensioned position, the element holds the suture strands along a substantially straight path to provide ease of sliding. In the relaxed shape-recovery position, the element holds the suture strands along a tortuous path. In some embodiments, the suture strands are held along the same path and in others, wherein the suture strands comprise a first suture strand and a second suture strand, the first strand follows a first tortuous path and the second strand follows a second tortuous path which differs from the first tortuous path. And, in some embodiments, the tortuous path has a zig zag form or other non-linear form.

**[0011]** A variety of forms of suture fastener are described. In some examples, the suture fastener comprises a fastening element comprising a coil. In some of the exemplary coils, each turn of the coil has a circular, elliptical, square or triangular shape, to name a few, when the element has the relaxed shape-recovery position. In addition, the coil may further comprise at least one suture retention loop, typically having a circular or elliptical shape. The suture retention loop(s) of each coil turn may be disposed in diametrical opposition when the element has the relaxed shape-recovery position, such as along a long axis of the elliptical shape when so shaped. Alternatively, the suture retention loop(s) may be spaced along each coil turn in a uniform or varied pattern. In other embodiments, each turn of the coil has a figure-eight shape comprising two lobes when the element has the relaxed shape-recovery position and one suture retention loop is disposed within each lobe. The suture retention loops are thus disposed in concentric alignment when the element has the tensioned position.

**[0012]** In other examples, the suture fastener comprises a fastening element which has a flat shape when in the tensioned position and the element has a curved or bent shape in the relaxed shape-recovery position. For example, the element may comprise an elongate wire, ribbon, rod, filament or shaft having two or more apertures along its length. In preferred embodiments, the element comprises a ribbon having a width in the range of approximately 0.076 to 0.305 cm (0.030 to 0.120 inches) and a thickness in the range of approximately 0.005 to 0.051 cm (0.002 to 0.020 inches). Suture strands are threaded through the apertures so that the element is slidable along the strands in the tensioned position. However, the curved shape of the element in the relaxed shape-recovery position prevents such sliding of the element and fixes the element in place.

**[0013]** In further examples, the suture fastener comprises two or more elements which interlock when the elements are in the relaxed shape-recovery position. Generally, the elements may be separated, straightened, held open or untwisted in the tensioned position so that the suture strands may be placed within or between them. In this arrangement, the elements may be moved relative to the suture strands to adjust the position of the elements along the strands. When the elements return to the relaxed shape-recovery position, the elements interlock around the strands so that the strands are held in a fixed position relative to the element and each other.

**[0014]** In embodiments, the suture fastener comprises an element which has a first portion having at least one first aperture and a second portion having at least one second aperture, wherein at least one first aperture is concentrically aligned with at least one second aperture when the element is in the tensioned position and the at least one first aperture is misaligned with the at least one second aperture when the element is in the relaxed shape-recovery position. To achieve this, the element has a cylindrical shape wherein at least part of the first portion overlaps at least part of the second portion when the element is in the tensioned position. In this configuration, suture strands may be threaded through the apertures in a stitching-type fashion. Thus, transition of the element to the relaxed configuration draws the portions apart placing the strands along a tortuous path.

**[0015]** In any of the above embodiments, transition from the tensioned position to the relaxed position may be achieved by any means, such as by release of a force on the element or by a change in temperature of the element.

**[0016]** A described method for securing two or more suture strands together comprises the steps of providing at least one fastening element comprised of a shape-recovery material, wherein the element is in a tensioned position for engaging the suture strands while allowing sliding of the element relative to the suture strands, engaging the suture strands with the element and transitioning the element to a relaxed shape-recovery position wherein the strands are in a fixed position relative to the element or to each other. The engaging step typically comprises positioning the suture strands along a path through at least a portion of the element. In some instances, the engaging step comprises positioning a first suture strand along a first path and a second suture strand along a second path which differs from the first path. When the element comprises a coil where each turn of the coil includes two suture retention loops, the positioning step may include positioning the suture strands through two or more suture retention loops. And when the suture retention loops of each coil turn are disposed in diametrical opposition when the element is in the relaxed shape-recovery position, the positioning step may include positioning the suture strands through successive suture retention loops so that the strands follow a path having a zig zag form when the element is in the relaxed shape-recovery position.

**[0017]** The providing step of the methods may include loading the element on a loading tool. Alternatively, the element may already be loaded on the loading tool and the providing step comprises providing the element loaded on or within a loading tool. In either situation, the transitioning step comprises releasing the element from the loading tool.

**[0018]** When the element comprises an elongate wire, ribbon, rod, filament or shaft, the engaging step may comprise positioning the suture strands near at least two elements so that the elements capture the suture strands during the transitioning step by interlocking with each other. When the element comprises an elongate wire, ribbon, rod, filament or shaft having two or more apertures along its length, the positioning step may comprise positioning the suture strands through at least two apertures, such as in a stitching fashion. Similarly, when the element has a first portion having at least one first aperture and a second portion having at least one second aperture, the positioning step may comprise positioning the suture strands through at least one first aperture and at least one second aperture. This is easily achieved when the element has at least one first aperture concentrically aligned with at least one second aperture and the positioning step comprises positioning the suture strands through apertures in a stitching fashion.

**[0019]** With any of the above described the fastening elements, the element may be slid along the suture strands to a desired position prior to transitioning to the relaxed shape-recovery position. Once transitioned, the position of the element along the suture strands may be adjusted. The adjusting step may comprise transitioning the element to the tensioned position and moving the element in relation to the suture strands.

**[0020]** A system is described for adjustably holding one or more suture strands comprises at least one fastening element comprised of a shape-recovery material, wherein the element has a tensioned position for engaging the suture strands while allowing sliding of the element relative to the suture strands and a relaxed shape-recovery position for holding the strands in a fixed position relative to the element or to each other, and a loading tool having a proximal end, a distal end and a lumen therethrough, wherein the element is loadable on the loading tool. In some examples, the loading tool further comprises a shaft near the distal end. In such instances, the element may comprise a coil which is mountable on the shaft. When each turn of the coil includes at least one suture retention loop, the coil maybe loadable on the loading tool by inserting the shaft through at least one of the suture retention loops.

**[0021]** The system may further comprise at least one suture strand which is engageable by the element. Here, the loading tool may comprise a shaft near the distal end which houses at least a portion of the lumen through which the suture strand is threadable.

**[0022]** A suture fastening system is described for adjustably holding one or more suture strands comprises a delivery catheter comprising a proximal end, a distal end, and a lumen therethrough; and a suture fastener loadable on the distal end of the delivery catheter, said fastener comprising a ratcheting mechanism which is adapted to hold a suture strand at a first location and then release the strand and hold the strand at a second location upon adjustment, wherein the first and second locations are a predetermined distance apart. In some examples, the system further comprises at least one suture strand, wherein the strand has at least a first protuberance disposed near the first location and a second protuberance disposed near the second location. The suture strand may comprise a fiber, thread, filament, wire or cord and at least one protuberance may be selected from the group consisting of knots, beads, balls, ribs, and spokes. Further, the suture strand or at least one protuberance may be comprised of a material selected from the group consisting of stainless steel, nitinol, metal, polymer, silicone, latex, epoxy, cotton, nylon, polyester, and polytetrafluoroethylene-. In some examples, the ratcheting mechanism comprises at least two flexible arms having stoppers mounted thereon which are engageable with the protuberance. In most of these instances, the suture fastener may be loadable within the lumen of the delivery catheter.

**[0023]** A method is described for adjustably holding a suture strand comprises the steps of providing a delivery catheter comprising a proximal end, a distal end, and a

lumen therethrough, loading a suture fastener on the distal end of the delivery catheter, said fastener comprising a ratcheting mechanism which is adapted to hold the suture strand at a first location and then hold the strand at a second location upon adjustment, wherein the first and second locations are a predetermined distance apart, and engaging the suture fastener with the suture strand at the first location. In some examples where the suture strand has at least a first protuberance disposed near the first location, wherein the ratcheting mechanism comprises at least two flexible arms each having a stopper mounted thereon which are engageable with the first protuberance, the loading step comprises positioning the suture strand so that the stopper engages the first protuberance. The method may further comprise adjusting the suture strand by advancing the strand through the fastener so that the fastener engages the strand at the second location. Thus, when the suture strand has at least a second protuberance disposed near the second location, wherein the ratcheting mechanism comprises at least two flexible arms each having a stopper mounted thereon which are engageable with the second protuberance, the loading step may comprise advancing the suture strand so that the stopper engages the second protuberance.

**[0024]** The described methods, systems and apparatuses may be provided in one or more kits for such use. The kits may comprise at least one fastening element comprised of a shape-recovery material, wherein the element has a tensioned position for engaging the suture strands while allowing sliding of the element relative to the suture strands and a relaxed shape-recovery position for holding the strands in a fixed position relative to the element or to each other, and instructions for use. Or, kits may comprise a ratcheting mechanism which is adapted to hold a suture strand at first location and then release the strand and hold the strand at a second location upon adjustment, wherein the first and second locations are a predetermined distance apart, and instructions for use. Optionally, such kits may further include any of the other described system components and any other relevant materials or items.

**[0025]** It may be appreciated that the suture strand(s) held by the fastener may be cut at any distance from the fastener. In this way, the suture strands and fastener may be left in place as a temporary or permanent implant. Cutting of the sutures may be achieved by any suitable means. For instance, a cutting blade may be included in the delivery catheter which deploys the fastener. Or, a separate cutting catheter, tool, instrument or device may be used. Thus, such a cutting means may be included in any of the described systems, apparatuses or kits.

**[0026]** Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0027]**

Figs. 1-2 illustrate a suture fastener.

Figs. 3-5 depict side views of a loading tool having a suture fastener loaded therein or thereon.

Figs. 6A-6C illustrate usage of a suture fastener in fixing valve leaflets together.

Figs. 7A-7B illustrate cross-sectional views of a fastening element having a coil shape.

Fig. 8 depicts a perspective view of a fastening element having a coil shape.

Fig. 9 illustrates a fixture for fabricating a fastening element having a coil shape.

Fig. 10 illustrates a cross-sectional view of a fastening element having a Figure-8 shape.

Fig. 11 depicts a perspective view of a fastening element having a Figure-8 shape.

Fig. 12 illustrates a fixture for fabricating a fastening element having a Figure-8 shape.

Fig. 13 illustrates suture strands held by a Figure-8 shaped element in a relaxed shape-recovery position.

Fig. 14 illustrates suture strands held by a Figure-8 shaped element in a relaxed shape-recovery position wherein each strand is held separately by the suture retention loops along separate paths.

Figs. 15A-15C illustrate a suture fastener comprising interlockable elements.

Figs. 16A-16B illustrate a suture fastener comprising an element having a flat shape when in a tensioned position and a curved shape when in a relaxed shape-recovery position.

Figs. 17A-17B illustrate a suture fastener embodying the invention comprising a cylindrically shaped element having first and second portions with apertures for positioning suture strands.

Figs. 18A-18B illustrate a triangularly shaped element having first and second portions with apertures for positioning suture strands.

Fig. 19 illustrates a delivery catheter for delivery and deployment of a fastening element.

Figs. 20A-20B depict textured suture strands.

Figs. 21A-21B illustrate examples of a ratchet for use with textured suture strands.

Fig. 22 illustrates a housing having a flange wherein the ratchet of Figs. 21A-21B is housed within.

Fig. 23 illustrates a pair of valve leaflets fixed together by a textured suture strand and ratcheted fasteners.

Figs. 24A-24B illustrate a pair of valve leaflets fixed together by a textured suture strand and a single ratcheted fastener.

Fig. 25 illustrates a kit.

Figs. 26A-26B, 27A-27B, 28A-28B illustrate additional examples of an element which holds suture strands, wherein each turn of the coil has various

numbers and arrangements of suture retention loops.

Fig. 29 illustrates an example wherein a suture strand is threaded through the suture retention loops in a pattern that does not follow the shape of the coil.

Fig. 30 illustrates an example of an element wherein the coil is formed by alternating the direction of the wind.

Figs. 31-32 illustrate turns of a coil having shapes other than circular or oval.

Fig. 33A illustrates a suture fastener embodying the invention in a tensioned position having portions which are overlapped so that at least one aperature is concentrically aligned with another aperture.

Fig. 33B illustrates the embodiment of Fig. 33A in a relaxed position wherein the apertures are misaligned.

DETAILED DESCRIPTION

**[0028]** Referring to Figs. 1-2, a suture fastener 100 is illustrated to provide an overview of general features. Here, the suture fastener 100 is comprised of a fastening element 102 having a coil shape. The element 102 is comprised of a shape-recovering material so that the element is able to return to a desired shape under certain conditions. For example, the shape-recovering material may be comprised of a shape-memory alloy, such as nitinol, or a spring-tempered steel. In this case, the element 102 may be placed in a tensioned position to form a first desired shape and release of the tension would allow the element 102 return to a relaxed shape-recovering position to form a second desired shape. These different shapes are useful in holding, adjusting and fastening one or more sutures.

**[0029]** For example, Fig. 1 illustrates a first suture strand 104 and a second suture strand 106 engaged by a fastening element 102. The element 102 has a coil shape wherein the suture strands 104, 106 are threaded through loops 108 of the coil while the element is maintained in a tensioned position. In this position, the loops 108 are generally aligned so that the suture strands 104, 106 are held along a substantially straight path. Thus, the element 102 may be slid back and forth, as indicated by arrows, relative to the suture strands 104, 106. Such sliding allows the element 102 to be advanced along the suture to a desired position for anchoring or fastening. Tension on the element 102 may then be released so that the element returns to a shape-recovering position. An example of such a position is shown in Fig. 2. Here, the element 102 holds the suture strands 104, 106 along a tortuous path having a zig zag form. In this position, the element 102 is not able to slide along the sutures as the tortuous path creates significant friction and resistance to sliding or slippage. Thus, the suture strands 104, 106 are fastened in place.

**[0030]** The suture fastener 100 may be introduced and deployed in a desired location with the use of a loading tool. In some examples, shown in Figs. 3-5, the loading tool 200 has a proximal end (not shown), a distal end 202 and a lumen 204 therethrough. In each of these cases, suture strands 104, 106 are typically inserted through the lumen 204 as shown. Referring to Fig. 3, the fastener 100 may be loaded within the lumen 204 so that the suture strands 104, 106 are threaded through the fastener 100. The fastener 100 may then be deployed by pushing the fastener 100 out of the distal end 202 of the loading tool 200. Referring to Fig. 4, the fastener 100 may be loaded or mounted on the outside of the loading tool 200. Here, the fastener 100 is shown coiled around a shaft 203 of the loading tool 200 which houses the lumen 204 containing suture strands 104, 106. Thus, the fastener 100 may then be deployed by pushing the fastener 100 off the distal end 202 of the loading tool 200 so that the fastener 100 engages the suture strands 104,106 at a desired location. Similarly, Fig. 5 illustrates a fastener 100 loaded on the outside of the loading tool 200. However, in this case the fastener 100 is shown coiled around the distal end 202 of the loading tool in a more compressed fashion. Such compression is desirable with some fastener 100 designs. Again, the fastener 100 may then be deployed by pushing the fastener 100 off the distal end 202 of the loading tool 200 so that the fastener 100 engages the suture strands 104, 106 at a desired location. It may be appreciated that the loading tool 200 may comprise a number of designs with the suture fastener 100 and/or suture strands 104,106 having a number of arrangements for deployment and function of the suture fastener 100.

**[0031]** Figs. 6A-6C illustrate a possible application for usage of the suture fastener 100. Here, valve leaflets LF are shown sutured together for treatment of valvular regurgitation. The first suture strand 104 and the second suture strand 106 are each attached to a valve leaflet LF by any suitable means. Rather than tying the suture strands 104, 106 together with a knot, a suture fastener 100 is used to fasten the strands 104, 106 together. In this example, the treatment procedure is performed with minimally invasive techniques wherein the valve leaflets are remotely accessed through the vascular system with the use of catheters. Thus, the loading tool 200 comprises a catheter which has been advanced through the vascular system to the leaflets LF. As shown in Fig. 6A, the loading tool 200, having the suture fastener 100 loaded within, approaches the site of the suture and the free ends of the suture strands 104, 106 are positioned within the lumen 204 of the loading tool 200. Referring now to Fig. 6B, the suture fastener 100 is then deployed at a desired location to hold the strands 104, 106 in a fixed position relative to the fastener 100 and/or to each other. The position of the fastener 100 may then be adjusted by sliding the fastener 100 along the suture strands 104, 106 to another desired location, such as closer to the leaflets LF as shown in Fig. 6C. Such adjustment is achieved by placing the fastener 100 in a tensioned position wherein the suture strands 104, 106 are engaged

but not fixed, moving the fastener 100 along the strands 104, 106 and then returning the fastener 100 to a relaxed shape-recovery position to hold the strands 104, 106 in a fixed position. Once the fastener 100 has reached its final position, the strands 104, 106 may be cut and the fastener 100 left in place, as illustrated in Fig. 6C.

**[0032]** As mentioned, the suture fastener 100 is comprised of at least one fastening element 102 comprised of any type of shape-recovery material. This includes but is not limited to nitinol wire, spring-tempered steel, polymers, Elgiloy ® (Elgin, IL) and the like. Likewise, the material may take any suitable form, such as round wire, flat wire, ribbon, hypotube, braid or cable. The fastener 100 may be comprised of 0.010-0.030 cm (0.004-0.012 inch) wire, preferably 0.020 cm (0.008 inch) superelastic nitinol wire. In some cases, the fastener 100 is heat-set by baking at approximately 450-560°C for around 5-10 min, preferably approximately 7 min, followed by cool water quenching. The shape-recovery material allows the element 102 to have a tensioned position for engaging the suture strands while allowing sliding of the element relative to the suture strands and a relaxed shape-recovery position for holding the strands in a fixed position relative to the element or to each other. It may be appreciated that the element 102 is transitionable between the tensioned and relaxed position by application and release of force on the element 102, by a change in temperature of the element or by any other applicable means.

**[0033]** The fastening element 102 may take any number of forms suitable for holding suture strands along various paths, including substantially straight to various degrees of tortuous. The element 102 may comprise a coil 250. As shown in cross-section in Figs. 7A-7B, each turn of the coil 250 may have, for example, an oval or elliptical shape, Fig. 7A, or a circular shape, Fig. 7B. In addition, each turn of the coil 250 may include at least one suture retention loop 252. Or, various turns of the coil 250 may include one or more suture retention loops 252 and other turns may include no suture retention loops. The suture retention loops 252 are often disposed in diametrical opposition when the element 102 is in the relaxed shape-recovery position. Fig. 8 provides a perspective view of the element 102 in the relaxed shape-recovery position, the element 102 having four turns of the coil 250, each turn having two diametrically opposed suture retention loops 252. During loading on or in the loading tool or at any other time when the element 102 is in the tensioned position, the suture retention loops 252 are disposed in concentric alignment. The element can undergo such deflection for loading on the loading tool with little or no permanent deformation due to the construction of the element 102, in particular the presence of the arched coil turn connecting the suture retention loops. Since the arches assume the deflection, the individual suture retention loops do not have as much strain placed on them and thus are able to more easily keep their shape. Concentric alignment of the loops 252 allows the suture strands 104, 106 to be advanced through the loops 252 along a substantially straight path for loading or repositioning of the element 102. Upon relaxation of the element 102, the strands are thus held along a tortuous path.

**[0034]** Fig. 9 illustrates a possible fixture 260 for fabricating the element 102. As shown, two 0.061 cm (0.024) in stainless steel mandrels 280 are press fit into holes 282 in a base 284 and trimmed to about 1 cm extension. The shape-recovery wire 286 is then wrapped around the fixture 260 as shown. Since each loop 252 is made with the wire 286 starting on the outside of the mandrels 280 and then returning to the outside of the mandrels 280, the suture would be trapped on the inside of the loop 252 and cannot slip out. Consequently, each loop 252 can be made with only one wind to keep the suture contained.

**[0035]** As shown in cross-section in Fig. 10, each turn of the coil 250 may have, for example, a Figure-8 shape having two lobes 255. In addition, each turn of the coil 250 may include at least one suture retention loop 252 disposed within each lobe 255. Again, such loops 252 are typically disposed in diametrical opposition when the element 102 is in the relaxed shape-recovery position. Fig. 11 provides a perspective view of the element 102 in the relaxed shape-recovery position, the element 102 having four turns of the coil 250, each turn having two diametrically opposed suture retention loops 252. It may be appreciated that the suture retention loops 252 may be absent from some turns of the coil to allow for greater deflection or strain in the tensioned position. During loading on or in the loading tool or at any other time when the element 102 is in the tensioned position, the suture retention loops 252 are disposed in nearly concentric alignment. Such alignment of the loops 252 allows the suture strands 104, 106 to be advanced through the loops 252 along a substantially straight path for loading or repositioning of the element 102. Upon relaxation of the element 102, the strands are thus held along a tortuous path. Fig. 12 illustrates a possible fixture 280 for fabricating the element 102. As shown, two 0.024 in stainless steel mandrels 280 are press fit into holes 282 in a base 284 and trimmed to about 1 cm extension. The shape-recovery wire 286 is then wrapped around the fixture 260 as shown.

**[0036]** Figs. 13-14 illustrate suture strands 104, 106 held by the element 102 along tortuous paths in the relaxed shape-recovery position. Referring to Fig. 13, the element 102 has a Figure-8 shape as described in relation to Figs. 10-12. Here, the first suture strand 104 and the second suture strand 106 are shown held together by suture retention loops 252 in each turn of the coil 250. When the element 102 is in the relaxed shape-recovery position, as shown, the strands 104, 106 are held together along a tortuous zig zag path. Referring to Fig. 14, the element 102 again has a Figure-8 shape but here the first suture strand 104 and the second suture strand 106 are held separately by suture retention loops 252. Thus, when the element 102 is in the relaxed shape-recovery

position, the first strand 104 follows a first tortuous path and the second strand 106 follows a second tortuous path which differs from the first tortuous path.

**[0037]** Figs. 26A-26B, 27A-27B, 28A-28B illustrate elements 102 wherein each turn of the coil 250 has various numbers and arrangements of suture retention loops 252. In one example shown in cross-section in Fig. 26A, each turn of the coil 250 has three suture retention loops 252. Fig. 26B provides a perspective view of the element 102 in the relaxed shape-recovery position, the element 102 having three turns of the coil 250, each turn having three suture retention loops 252. Also shown is a suture strand 104 threaded through the suture retention loops 252. In another example shown in cross-section in Fig. 27A, each turn of the coil 250 has four suture retention loops 252. Fig. 27B provides a perspective view of the element 102 in the relaxed shape-recovery position, the element 102 having three turns of the coil 250, each turn having four suture retention loops 252. Also shown is a suture strand 104 threaded through the suture retention loops 252. And, in yet another example shown in cross-section in Fig. 28A, each turn of the coil 250 has five suture retention loops 252. Fig. 28B provides a perspective view of the element 102 in the relaxed shape-recovery position, the element 102 having four turns of the coil 250, each turn having five suture retention loops 252. Again, also shown is a suture strand 104 threaded through the suture retention loops 252. Thus, generally, the more suture retention loops present, the more closely the threaded suture strand 104 follows the shape of the coil. However, as shown in Fig. 29, the suture strand 104 may be threaded through the loops 252 in a pattern that does not follow the shape of the coil 250, and additionally the suture strand 104 may not be threaded through all of the loops 252. It may be appreciated that each turn of the coil may have any number of retention loops and the suture retention loops 252 may be absent from some turns of the coil to allow for greater deflection or strain in the tensioned position.

**[0038]** Fig. 30 illustrates an element 102 wherein the coil 250 is formed by alternating the direction of the wind. As shown, the coil 250 reverses direction of the wind at reverse points 251. This provides a slightly different relaxed shape-recovery position from the standard coil shape and responds differently when in the tensioned position. As shown, the suture retention loops 252 may still be located within each turn of the coil.

**[0039]** It may also be appreciated that the turns of the coil 250 may be shaped other than circular or oval. For example, as shown in Fig. 31, each turn of the coil 250 may be square or, as shown in Fig. 32, each turn of the coil 250 may be triangular. Suture retention loops 252 may be located along each turn, as shown, and a suture strand 104 is then threaded through the loops 252. Again, it may be appreciated that loops 252 may not be located along every turn of the coil and the suture strand 104 may be threaded through some or all of the loops in any configuration.

**[0040]** In other examples, the suture fastener 100 comprises two or more elements 300 which are interlockable, an example of which is illustrated in Figs. 15A-15C. Referring to Fig. 15A, the fastener 100 is comprised of two elements 300 which are curved so that they interlock as shown when the element is in the relaxed shape-recovery position. Each element 300 may be comprised of an elongate wire, ribbon, rod, filament, shaft, braid, strand, cable, hypotube, weave, or mesh, to name a few. As shown in Fig. 15B, the elements 300 maybe separated, straightened, held open or untwisted in the tensioned position so that suture strands 104, 106 may be placed within or between them. In this arrangement, the strands 104, 106 may be moved or adjusted relative to the elements 300 or each other. When the elements 300 return to the relaxed shape-recovery position, the elements 300 interlock around the strands, as shown in Fig. 15C, so that the suture strands 104, 106 are held in a fixed position relative to the element 300 and each other. Similarly, in another example, the fastener 100 is comprised of one element which has a straight configuration in the tensioned position and a curved configuration in the relaxed shape-recovery position so that the curved configuration can hold suture strands 104,106 in a fixed position.

**[0041]** In additional examples, the suture fastener 100 comprises an element 400 which has a flat shape when in the tensioned position and a curved or bent shape when in the relaxed shape-recovery position, an example of which is illustrated in Figs. 16A-16B. Referring to Fig. 16A, the element 400 is comprised of elongate wire, ribbon, rod, filament, shaft, mesh or woven sheet, to name a few, having two or more apertures 402 along its length. In a preferred example, the element 400 comprises a ribbon having a width in the range of approximately 0.076 to 0.305 cm (0.030 to 0.120 inches) and a thickness in the range of approximately 0.005 to 0.051 cm (0.002 to 0.010 inches). The suture strands 104,106 are threaded through the apertures 402 in an alternating fashion as shown. Alternatively, the strands 104,106 may be threaded in another arrangement which engages the strands 104, 106 with the element 400 yet allows the strands 104, 106 to slide relative to the element 400, as illustrated by arrows. When the element 400 forms the relaxed shape-recovery position, shown in Fig. 16B, the element 400 forms a curved or bent shape which prevents the strands 104, 106 from sliding relative to the element 400. Thus, the strands 104,106 are fixed in place.

**[0042]** In embodiments, illustrated in Figs. 17A-17B, the suture fastener 100 comprises an element 500 which has a first portion 502 having at least one first aperture 504 and a second portion 506 having at least one second aperture 508. Referring to Fig. 17A, the element 500 may have a cylindrical shape wherein the portions 502,506 comprise end flaps as shown. By placing the element 500 in the tensioned position, the portions 502, 506 are overlapped so that at least one first aperture 504 is concentrically aligned with at least one second aperture 508. Suture strands 104, 106 threaded through the apertures

504, 508, as shown, may thus slide in relation to the element 500 for adjustment of the position of the element 500. When the element 500 is placed in the relaxed shape-recovery position, shown in Fig. 17B, the at least one first aperture 504 is then misaligned with the at least one second aperture 508. In this configuration, it is much more difficult for the suture strands 104, 106 to slide relative to the element 500 so the strands 104, 106 are essentially fixed in place. Similarly, as shown in Figs, 18A-18B, the exemplary element 500 may have a triangular shape wherein the portions 502, 506 comprise end flaps as shown. In this example, the element 500 functions as in Figs. 17A-17B respectively.

**[0043]** In another embodiment, illustrated in Figs. 33A-33B, the element 500 again has a first portion 502 having at least one first aperture 504 and a second portion 506 having at least one second aperture 508. Referring to Fig. 33A, the element 500 may have a cylindrical shape wherein the portions 502, 506 comprise end flaps as shown. By placing the element 500 in the tensioned position, the portions 502, 506 are overlapped so that at least one first aperture 504 is concentrically aligned with at least one second aperture 508. The element may be held in the tensioned position by the insertion of a mandrel 505, as shown, or by any other suitable means. Suture strands 104, 106 threaded through the apertures 504, 508, as shown, may thus slide in relation to the element 500 for adjustment of the position of the element 500. When the mandrel 505 is removed element 500 is placed in the relaxed shape-recovery position, shown in Fig. 33B, the at least one first aperture 504 is then misaligned with the at least one second aperture 508 by inward recoiling of the element 500. In this configuration, it is much more difficult for the suture strands 104,106 to slide relative to the element 500 so the strands 104, 106 are essentially fixed in place.

**[0044]** Fig. 19 illustrates an example of a delivery catheter 520 for delivery and deployment of the element 500. Here, the delivery catheter 520 comprises a push rod 522, having a slot 524 therethrough, surrounded by an outer tube 526. The element 500 is loaded, in the compressed or tensioned position, within the outer tube 526 distal to the push rod 522. Suture strands 104, 106 are threaded through the element 500, as previously described in relation to Figs. 17A-17B and Figs. 18A-18B, and through the slot 524 in the push rod 522. Once the sutures 104, 106 are positioned in the tissue (not shown), such as through valve leaflets wherein anchors 530 at the ends of the sutures 104, 106 rest against the underside of the leaflets, the element 500 may be positioned at a desired location along the suture strands 104,106. Once in this position, the element 500 is deployed from the catheter 520 by pushing the element 500 out of the outer tube 526 with the push rod 522. A cutting mechanism 532 may also be integral with the push rod 522 to cut the suture strands 104, 106 and leave the element 500 in place.

**[0045]** In additional examples, the suture fastener 100 comprises a ratcheting mechanism 600 for securing a textured suture strand 602. Typically, such suture strands 602 are comprised of a fiber, thread, filament, wire or cord and may be textured by any means to provide a surface having protuberances 603 for securing with the ratcheting mechanism 600. Protuberances may include knots, beads, balls, ribs and spokes. For example, a suture strand 602 having a ribbed texture is shown in Fig. 20A, and having a beaded texture is shown in Fig. 20B. The suture strand 602 or at least one protuberance 603 may be comprised of any suitable material, such as stainless steel, metal, polymer, silicone, latex, epoxy, cotton, nylon, polyester and Teflon, to name a few. For example, the suture strands 602 may be formed by extruding the desired texture with a rigid polymer over a stainless steel core wire. Alternatively, knots may be tied in increments along a flexible suture strand to provide a suitable texture.

**[0046]** Figs. 21A-21B illustrate examples of the ratcheting mechanism 600 for use with the textured suture strand 602. As shown in Figs. 21A -21B, the ratcheting mechanism 600 may include a cylindrical tube 604 having flexible arms 606 thereattached. Stoppers 608 are attached near the distal end of the arms 606 as shown. The stoppers 608 are used to nestle between the protuberances 603 of the suture strand 602 and hold the strand 602 in place. For example, the ratcheting mechanism 600 maybe adapted to hold the suture strand 602 at a first location and then release the strand 602 and hold the strand 602 at a second location upon adjustment, wherein the first and second locations are a predetermined distance apart. Referring to Fig. 22, the suture fastener 100 may further comprise a housing 610 having a flange 612 for tissue contact wherein the ratcheting mechanism 600 is housed within. The fastener 100 may be mounted on the distal end 622 of a delivery catheter 520 for placement in a desired location along a suture strand 602. As shown in Fig. 23, valve leaflets LF may be fixed together by a suture strand 602. Suture fasteners 100 may be positioned along the suture strand 602, as shown, so that the flanges 612 contact the surfaces of the leaflets LF. The position of the fasteners 100 may be adjusted by advancing the suture strand 602 through the ratcheting mechanism 600. The suture strand 602 is then held in place by action of the stoppers 608 in the protuberances 603 as described above. Similarly, as shown in Figs. 24A-24B, one suture fastener 100 may be used to fix a pair of leaflets together. In Fig. 24A, the suture strand 602 is passed through each of the leaflets LF wherein one end of the strand 602 forms a loop 624 through which the other free end 626 of the strand 602 is passed. The fastener 100 is then positioned along this free end 626 and adjusted and/or secured as described in relation to Fig. 23. In Fig. 24B, the suture strand 602 is passed through each of the leaflets LF so that both free ends 626 are on one side of the leaflets LF. The fastener 100 is then positioned along both free ends 626, as shown, and adjusted and/or secured as described in relation to Fig. 23.

**[0047]** Referring now to Fig. 25, kits 700 comprise at least a suture fastener 100 and instructions for use IFU. Such kits may include more than one suture fastener which may include different features, such as element 102 or ratcheting mechanism 600. Optionally, the kits may further include one or more of any of the other system components described above, such as a loading tool 200, a suture strands 104, 106, a textured suture strand 602, and/or a delivery catheter 520. In addition, other items may be included related to the medical procedure, such as catheters, guidewires, introducers, dilators, and needles, to name a few. The instructions for use IFU will set forth any of the methods as described above, and all kit components will usually be packaged together in a pouch 702 or other conventional medical device packaging. Usually, those kit components, such as suture fasteners 100, which will be used in performing the procedure on the patient will be sterilized and maintained within the kit. Optionally, separate pouches, bags, trays or other packaging may be provided within a larger package, where the smaller packs may be opened separately to separately maintain the components in a sterile fashion.

## Claims

1. A suture fastener (100) for adjustably holding one or more suture strands (104 106) comprising: a cylindrical fastening element (500) comprised of a shape-recovery material, wherein the cylindrical fastening element (500) has overlapping first and second portions, (502, 506) the first portion (502) having at least one first aperture (504) and the second portion (506) having at least one second aperture (508), wherein the cylindrical fastening element (500) has a tensioned position in which the first and second portions (502 and 506) overlap so that the first and second apertures (504, 508) are concentrically aligned with one another to enable one or more suture strands (104, 106) to be threaded through the concentrically aligned first and second apertures (504, 508) so that the cylindrical fastening element (500) engages the one or more suture strands (104, 106) whilst allowing sliding of the fastening element (100) relative to the suture strand or strands (104, 106) to enable adjustment of the position of the cylindrical fastening element (100), and wherein the cylindrical fastening element (500) has a relaxed shape-recovery position in which the first and second apertures (504, 508) are misaligned to hold the suture strand or strands (104, 106) in a fixed position relative to the cylindrical fastening element (500).

2. A suture fastener as in claim 1, wherein the cylindrical fastening element (500) holds the suture strand or strands (104, 106) along a substantially straight path in the tensioned position.

3. A suture fastener as in claim 1 or 2, wherein the cylindrical fastening element (500) holds the suture strand or strands (104, 106) along a tortuous path in the relaxed shape-recovery position.

4. A suture fastener as in claim 3, wherein the tortuous path has a circumferentially offset form.

5. A suture fastener according to any preceding claim, wherein the first portion (502) has a series of first apertures (504) and the second portion (506) has a series of second apertures (508), each first aperture (504) being concentrically aligned with a corresponding one of the second apertures (508) in the tensioned position.

6. A suture fastener according to any preceding claim, wherein the cylindrical fastening element (500) comprises a shape-memory metal or a spring-tempered steel.

7. A suture fastener as in claim 1, wherein the cylindrical fastening element (500) is transitionable from the tensioned position to the relaxed position by release of a force on the element.

8. A suture fastener as in claim 1, wherein the cylindrical fastening element (500) is transitionable from the tensioned position to the relaxed position by a change in temperature of the element.

## Patentansprüche

1. Nahtbefestigungsvorrichtung (100) zum einstellbaren Halten eines oder mehrerer Nahtstränge (104, 106), das Folgendes umfasst: ein zylindrisches Befestigungselement (500), das aus einem Formwiederherstellungsmaterial besteht, wobei das zylindrische Befestigungselement (500) überlappende erste und zweite Abschnitte (502, 506) aufweist, wobei der erste Abschnitt (502) mindestens eine erste Öffnung (504) aufweist und der zweite Abschnitt (506) mindestens eine zweite Öffnung (508) aufweist, wobei das zylindrische Befestigungselement (500) eine gespannte Position aufweist, in der die ersten und zweiten Abschnitte (502 und 506) überlappen, so dass die ersten und zweiten Öffnungen (504, 508) konzentrisch zueinander ausgerichtet sind, damit ein oder mehrere Nahtstränge (104, 106) durch die konzentrisch ausgerichteten ersten und zweiten Öffnungen gefädelt werden können, so dass das zylindrische Befestigungselement (500) in den einen oder die mehreren Nahtstränge (104, 106) eingreift, während ein Gleiten des Befestigungselements (100) relativ zu dem Nahtstrang bzw. den Nahtsträngen (104, 106) ermöglicht wird, um eine Einstellung der Position des zylindrischen Befestigungsele-

ments (100) zu ermöglichen, und wobei das zylindrische Befestigungselement (500) eine entspannte Formwiederherstellungsposition aufweist, in der die ersten und zweiten Öffnungen (504, 508) fehlausgerichtet sind, um den Nahtstrang bzw. die Nahtstränge (104, 106) in einer festen Position relativ zu dem zylindrischen Befestigungselement (500) zu halten.

**2.** Nahtbefestigungsvorrichtung nach Anspruch 1, wobei das zylindrische Befestigungselement (500) den Nahtstrang bzw. die Nahtstränge (104, 106) entlang eines im Wesentlichen geraden Pfades in der gespannten Stellung hält.

**3.** Nahtbefestigungsvorrichtung nach Anspruch 1 oder 2, wobei das zylindrische Befestigungselement (500) den Nahtstrang bzw. die Nahtstränge (104, 106) entlang eines gewundenen Pfads in der entspannten Formwiederherstellungsposition hält.

**4.** Nahtbefestigungsvorrichtung nach Anspruch 3, wobei der gewundene Pfad eine im Umfang versetzte Form aufweist.

**5.** Nahtbefestigungsvorrichtung nach einem der vorhergehenden Ansprüche, wobei der erste Abschnitt (502) eine Reihe von ersten Öffnungen (504) aufweist, und der zweite Abschnitt (506) eine Reihe von zweiten Öffnungen (508) aufweist, wobei jede erste Öffnung (504) mit einer entsprechenden der zweiten Öffnungen (508) in der gespannten Position konzentrisch ausgerichtet ist.

**6.** Nahtbefestigungsvorrichtung nach einem der vorhergehenden Ansprüche, wobei das zylindrische Befestigungselement (500) ein Formgedächtnismetall oder einen federharten Stahl umfasst.

**7.** Nahtbefestigungsvorrichtung nach Anspruch 1, wobei das zylindrische Befestigungselement (500) nach Freigabe einer Kraft auf das Element aus der gespannten Position in die entspannte Position versetzt werden kann.

**8.** Nahtbefestigungsvorrichtung nach Anspruch 1, wobei das zylindrische Befestigungselement (500) durch Änderung der Temperatur des Elements aus der gespannten Position in die entspannte Position versetzt werden kann.

**Revendications**

**1.** Dispositif de fermeture pour sutures (100) permettant de retenir de manière ajustable un ou plusieurs brins de suture (104, 106) comportant : un élément de fermeture cylindrique (500) constitué d'un matériau à restitution de forme, dans lequel l'élément de fermeture cylindrique (500) a des première et seconde parties se chevauchant (502, 506), la première partie (502) ayant au moins une première ouverture (504) et la seconde partie (506) ayant au moins une seconde ouverture (508), dans lequel l'élément de fermeture cylindrique (500) a une position sous tension dans laquelle les première et seconde parties (502 et 506) se chevauchent de sorte que les première et seconde ouvertures (504, 508) sont alignées de manière concentrique l'une par rapport à l'autre pour permettre à un ou plusieurs brins de suture (104, 106) d'être enfilés au travers des première et seconde ouvertures (504, 508) alignées de manière concentrique de sorte que l'élément de fermeture cylindrique (500) entre en prise avec lesdits un ou plusieurs brins de suture (104, 106) tout en permettant le coulissement de l'élément de fermeture (100) par rapport au brin ou aux brins de suture (104, 106) pour permettre l'ajustement de la position de l'élément de fermeture cylindrique (100), et dans lequel l'élément de fermeture cylindrique (500) a une position sans tension à restitution de forme dans laquelle les première et seconde ouvertures (504, 508) sont mal alignées pour maintenir le brin ou les brins de suture (104, 106) dans une position fixe par rapport à l'élément de fermeture cylindrique (500).

**2.** Dispositif de fermeture pour sutures selon la revendication 1, dans lequel l'élément de fermeture cylindrique (500) retient le brin ou les brins de suture (104, 106) le long d'une trajectoire sensiblement droite dans la position sous tension.

**3.** Dispositif de fermeture pour sutures selon la revendication 1 ou 2, dans lequel l'élément de fermeture cylindrique (500) retient le brin ou les brins de suture (104, 106) le long d'une trajectoire tortueuse dans la position sans tension à restitution de forme.

**4.** Dispositif de fermeture pour sutures selon la revendication 3, dans lequel la trajectoire tortueuse a une forme décalée dans le sens de la circonférence.

**5.** Dispositif de fermeture pour sutures selon l'une quelconque des revendications précédentes, dans lequel la première partie (502) a une série de premières ouvertures (504) et la seconde partie (506) a une série de secondes ouvertures (508), chaque première ouverture (504) étant alignée de manière concentrique sur une ouverture correspondante des secondes ouvertures (508) dans la position sous tension.

**6.** Dispositif de fermeture pour sutures selon l'une quelconque des revendications précédentes, dans lequel l'élément de fermeture cylindrique (500) comporte un métal à mémoire de forme ou un acier revenu à l'état ressort.

**7.** Dispositif de fermeture pour sutures selon la revendication 1, dans lequel l'élément de fermeture cylindrique (500) est en mesure de passer de la position sous tension à la position sans tension par la libération d'une force sur l'élément.

**8.** Dispositif de fermeture pour sutures, selon la revendication 1, dans lequel l'élément de fermeture cylindrique (500) est en mesure de passer de la position sous tension à la position sans tension par un changement de température de l'élément.

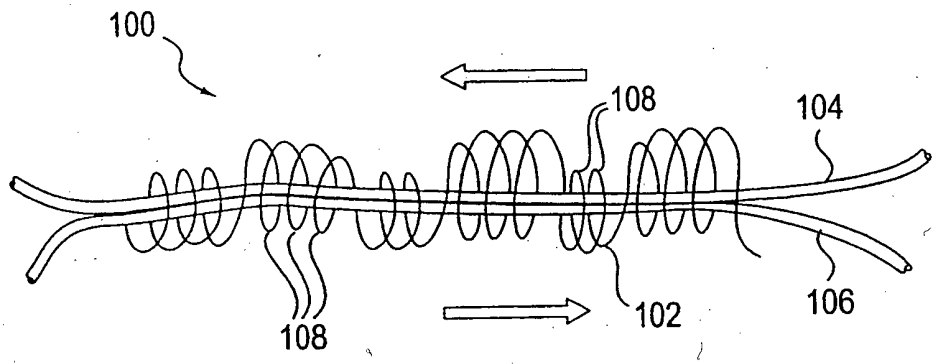



FIG. 1

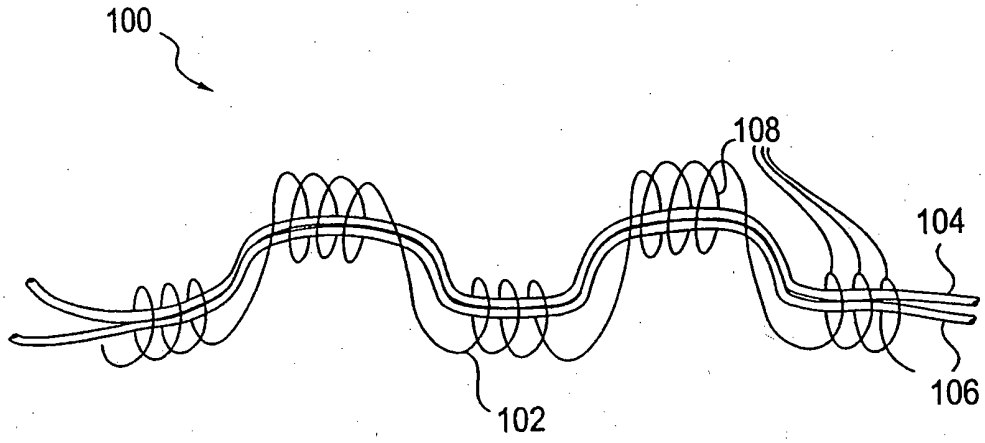



FIG. 2

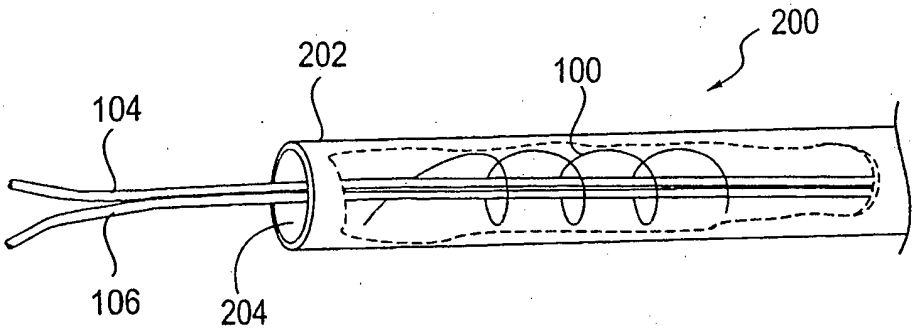



FIG. 3

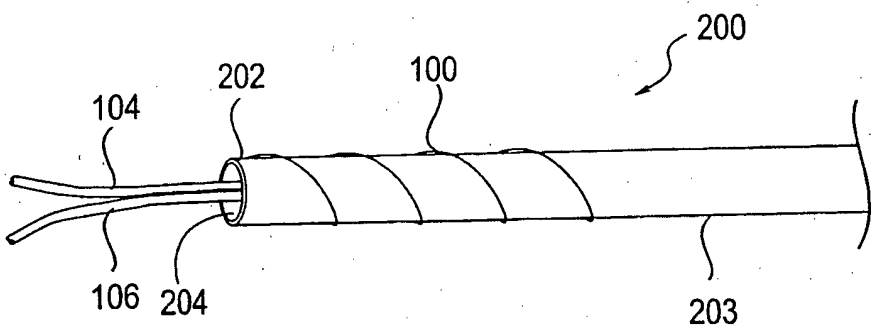



FIG. 4

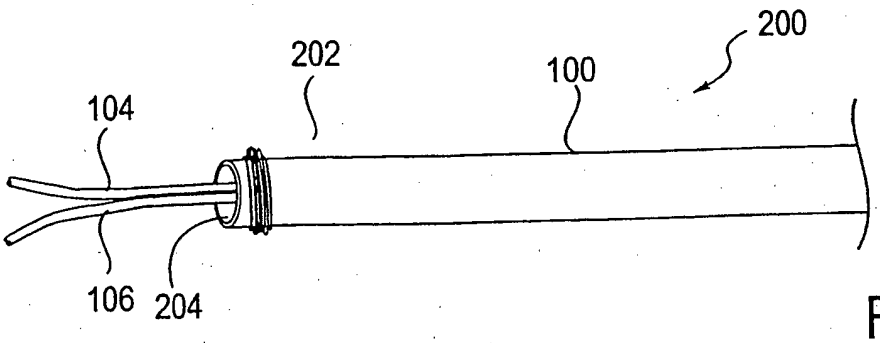



FIG. 5

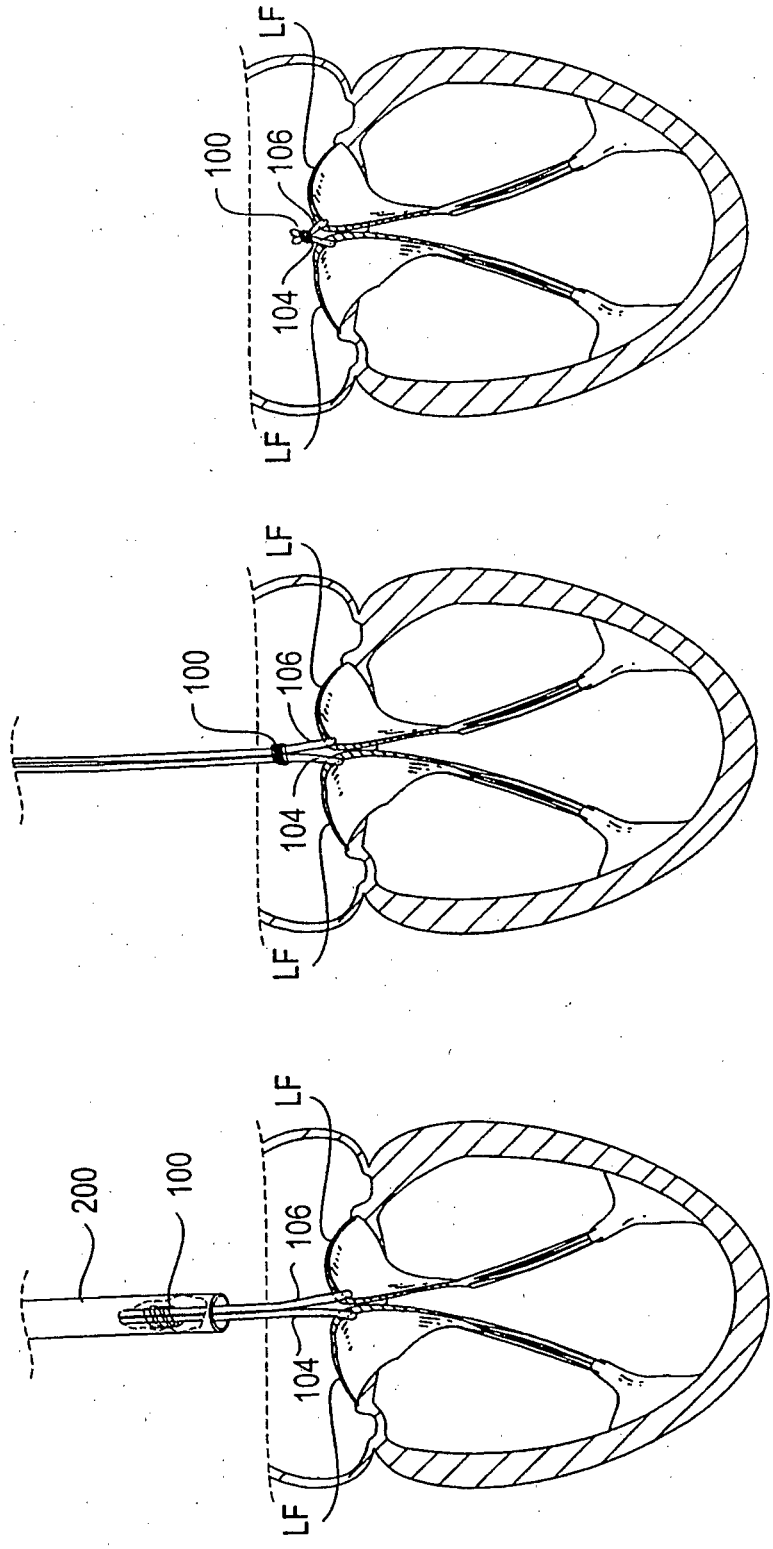



FIG. 6C

FIG. 6B

FIG. 6A

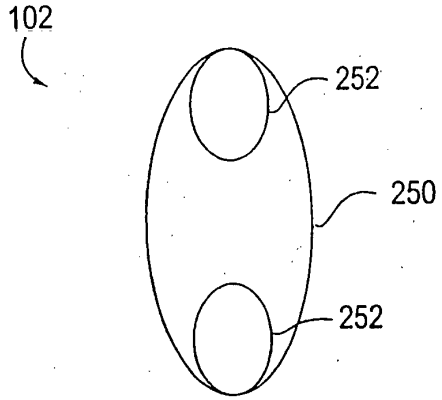



FIG. 7A

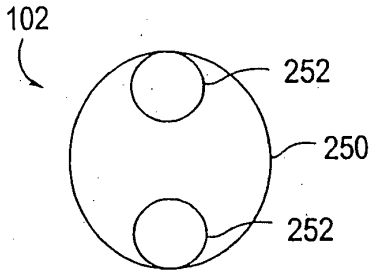



FIG. 7B

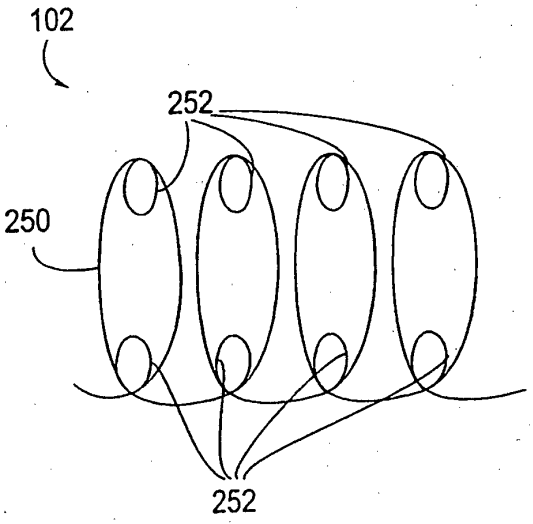



FIG. 8

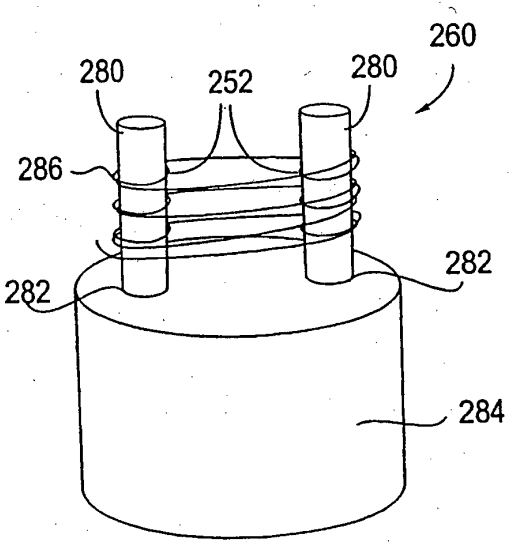



FIG. 9

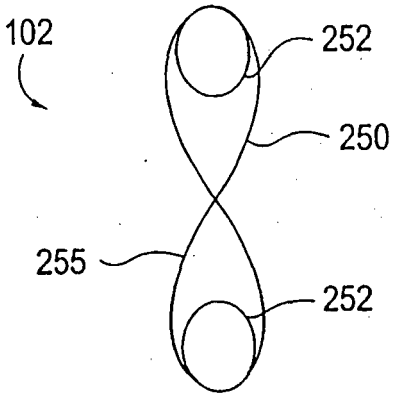



FIG. 10

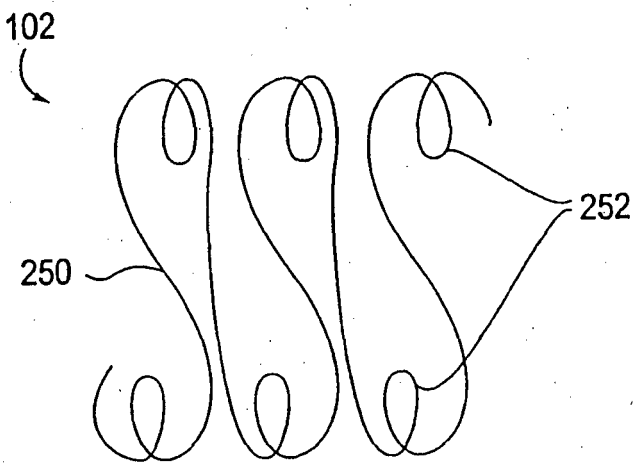



FIG. 11

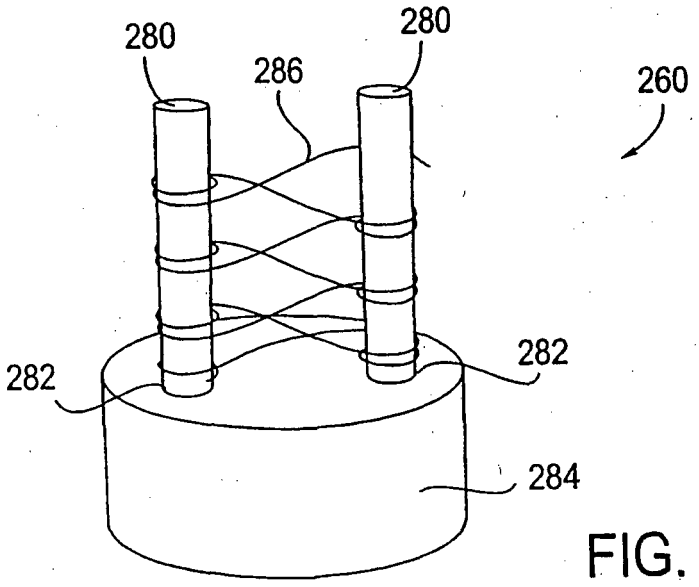



FIG. 12

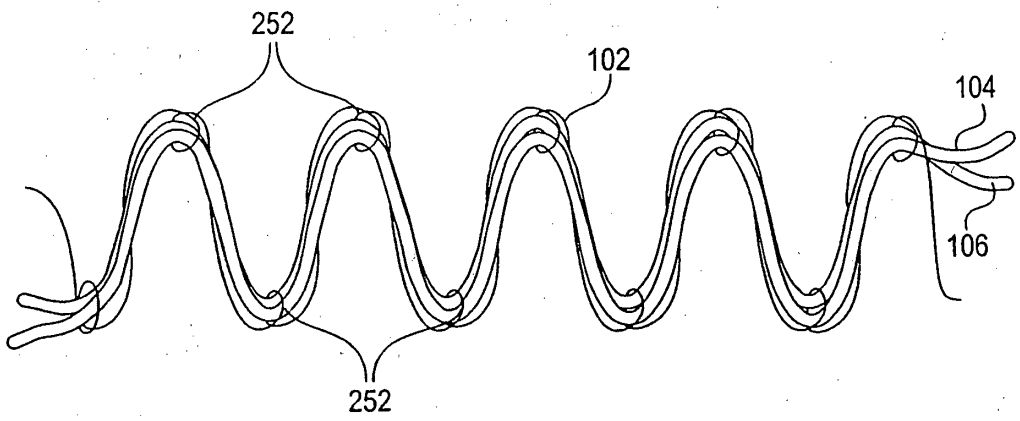



FIG. 13

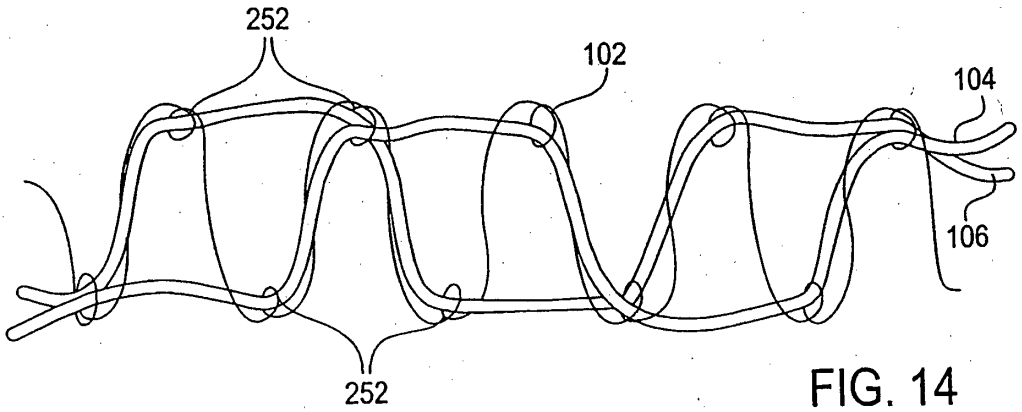



FIG. 14

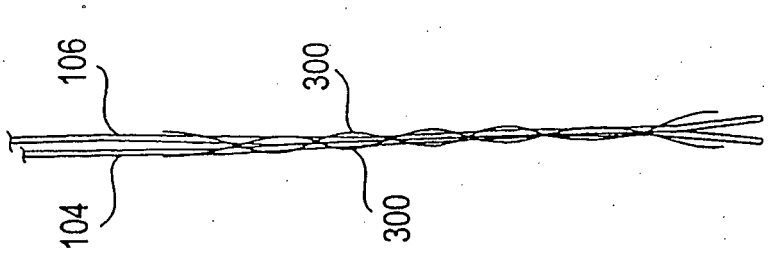



FIG. 15C

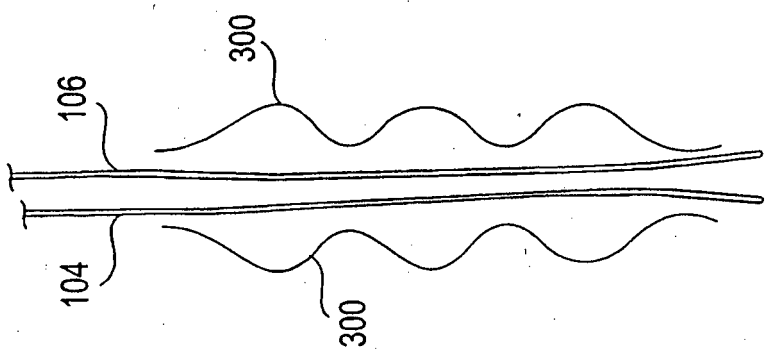



FIG. 15B

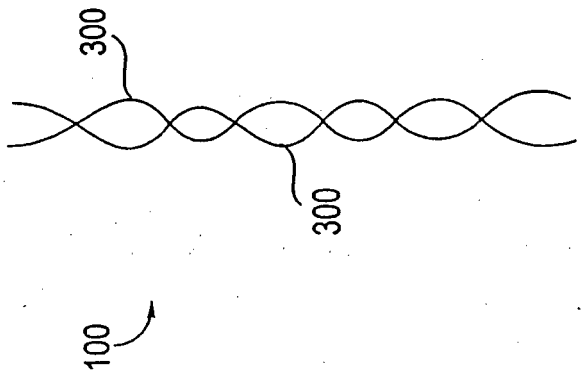



FIG. 15A

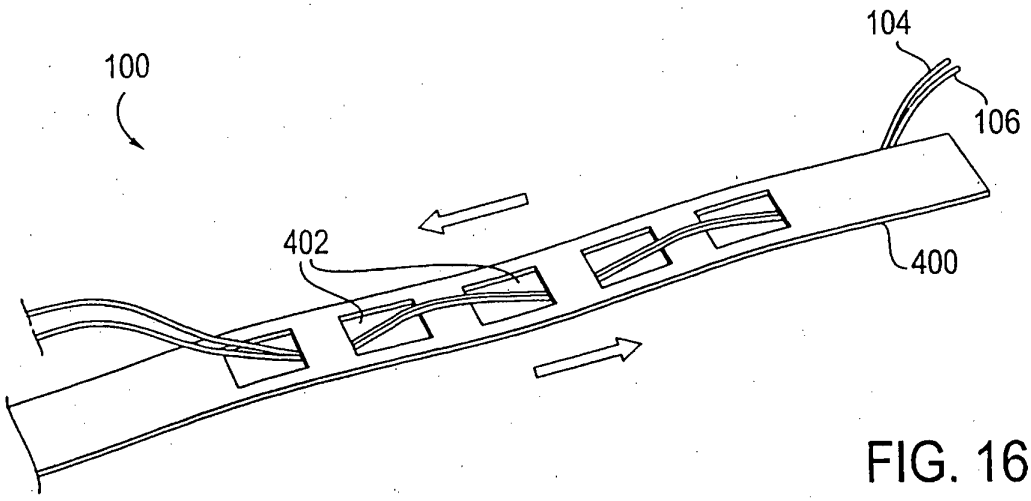



FIG. 16A

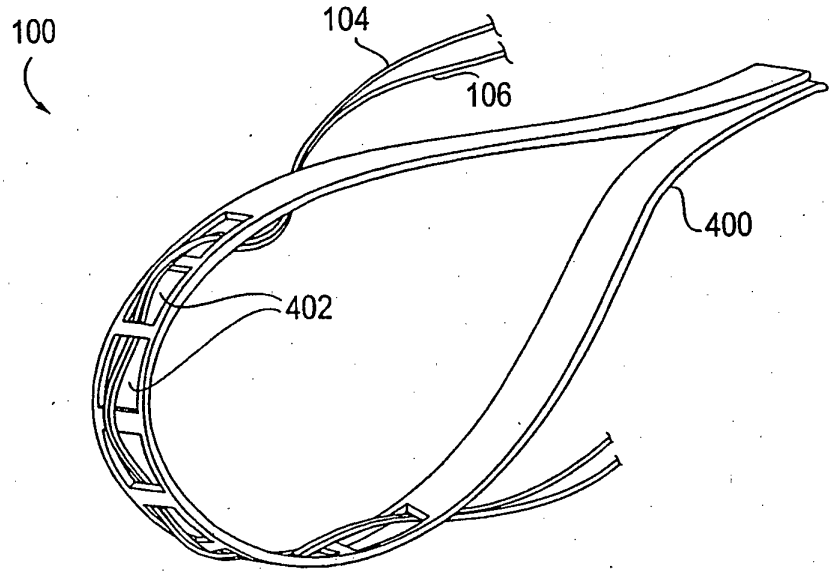



FIG. 16B

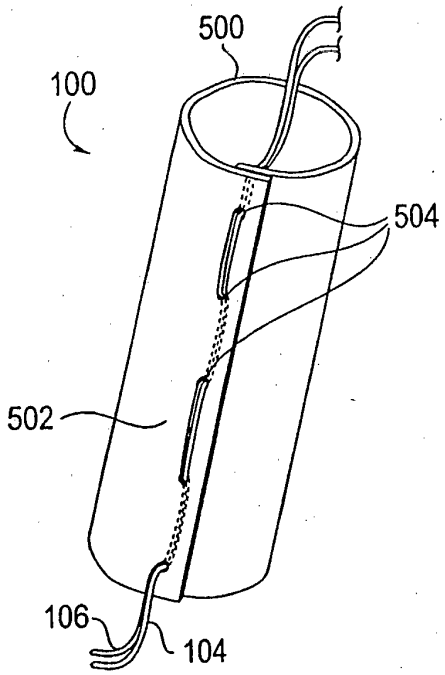



FIG. 17A

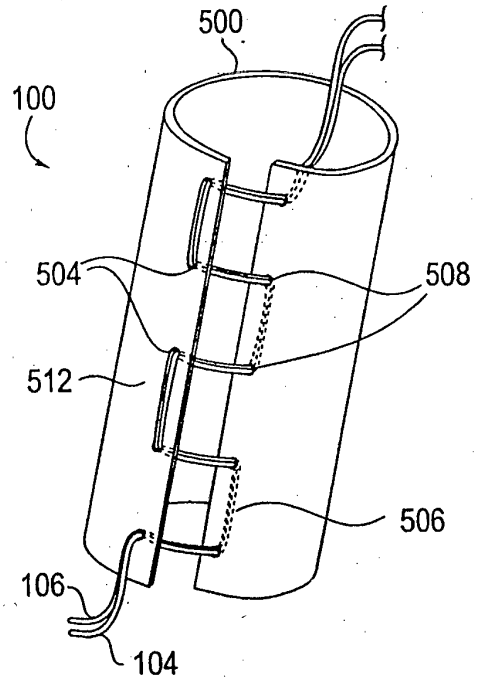



FIG. 17B

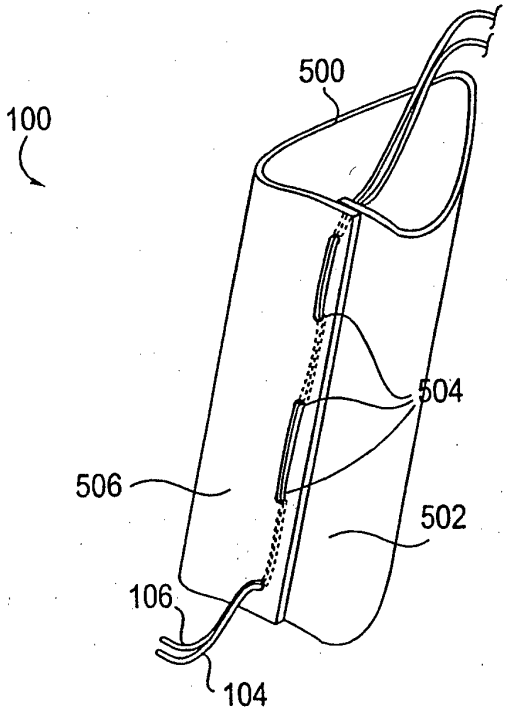



FIG. 18A

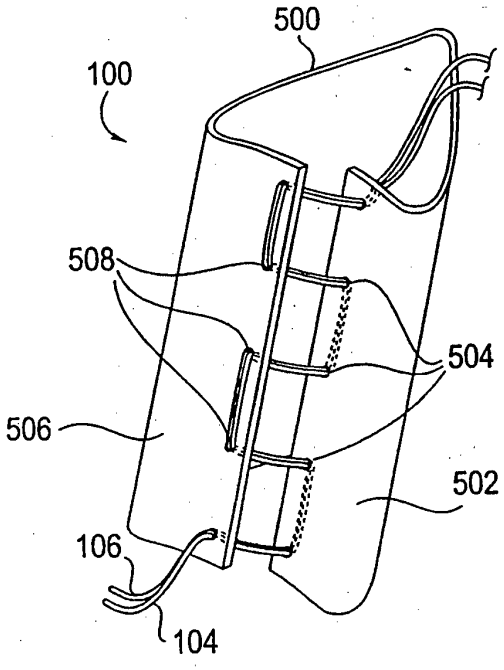



FIG. 18B

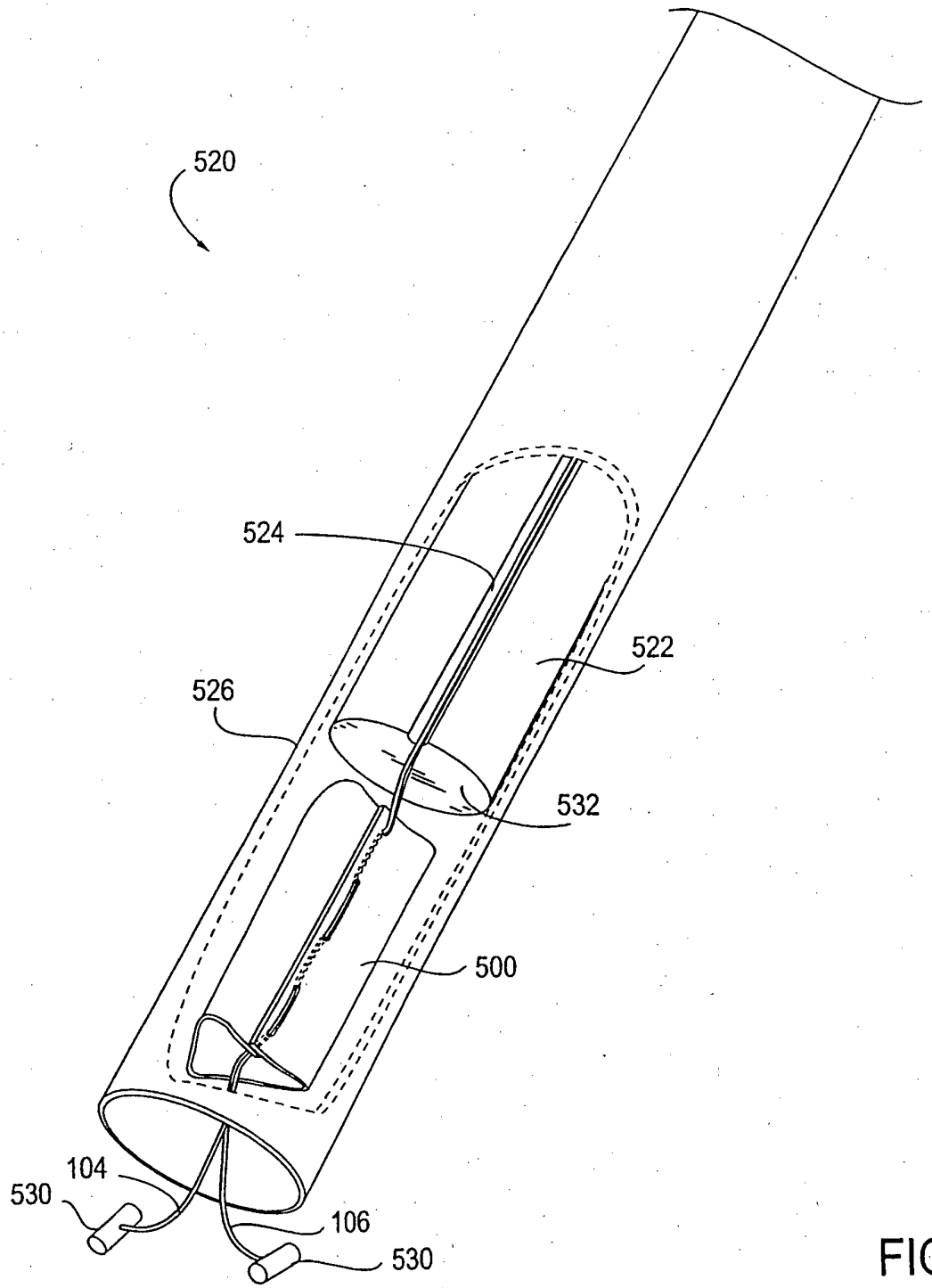



FIG. 19

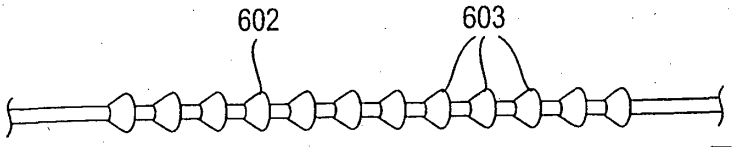



FIG. 20A

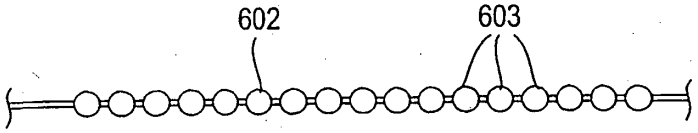



FIG. 20B

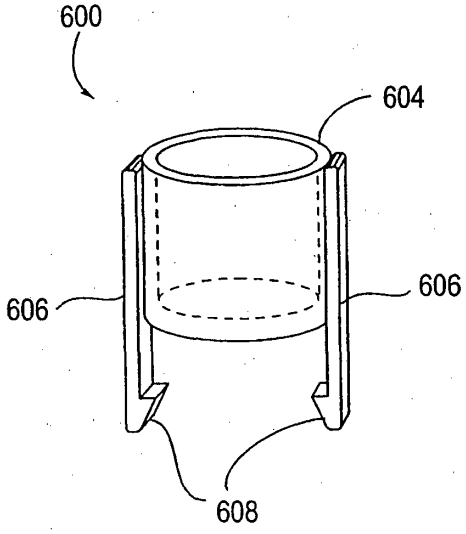



FIG. 21A

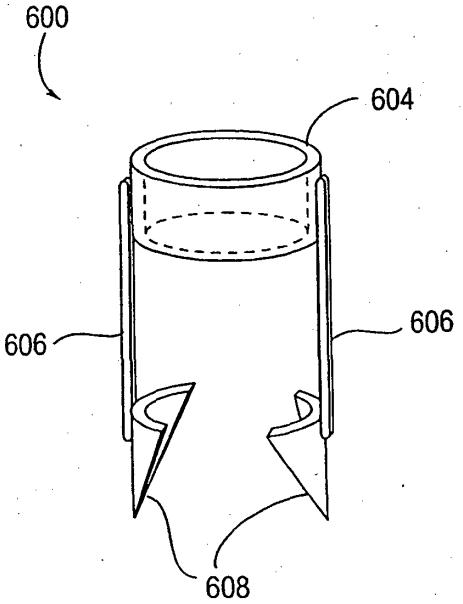



FIG. 21B

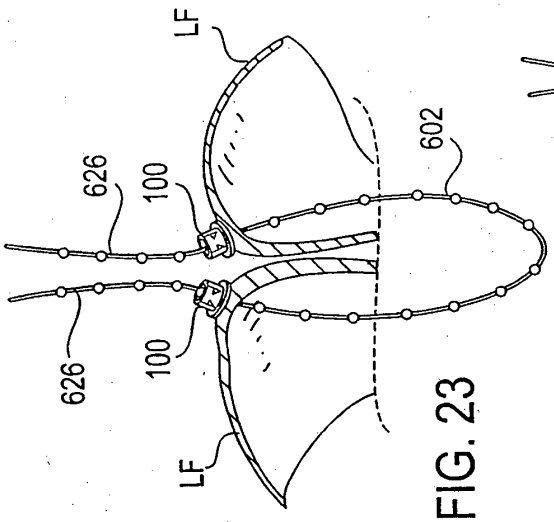



FIG. 23

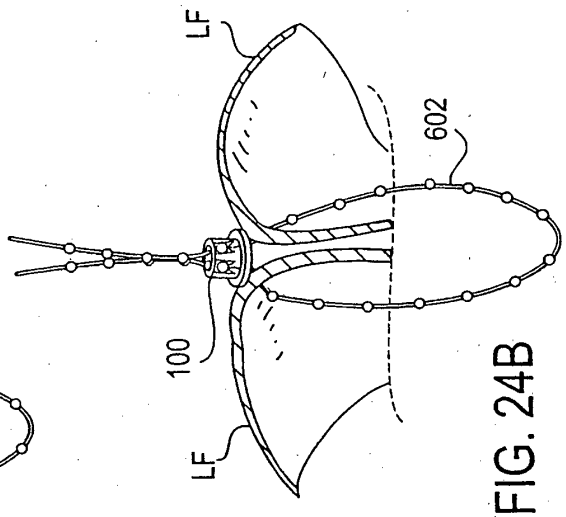



FIG. 24B

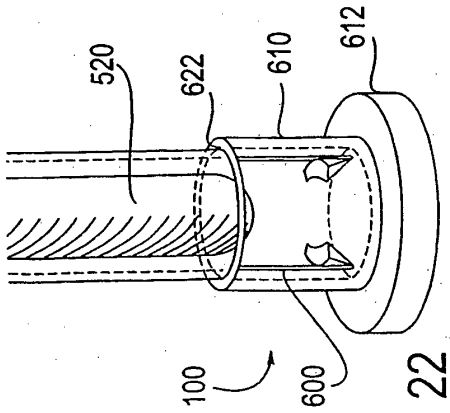



FIG. 22

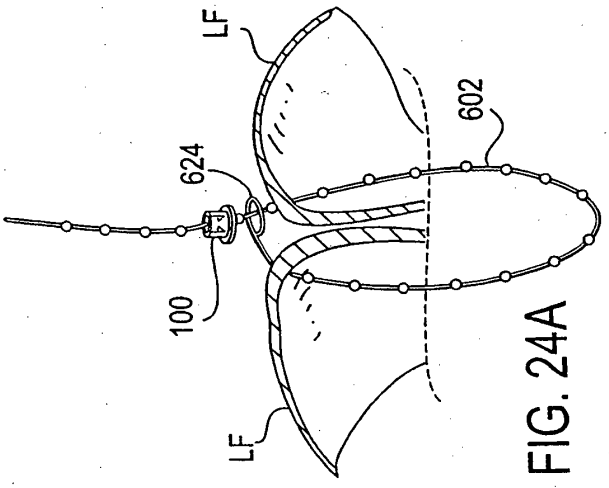



FIG. 24A

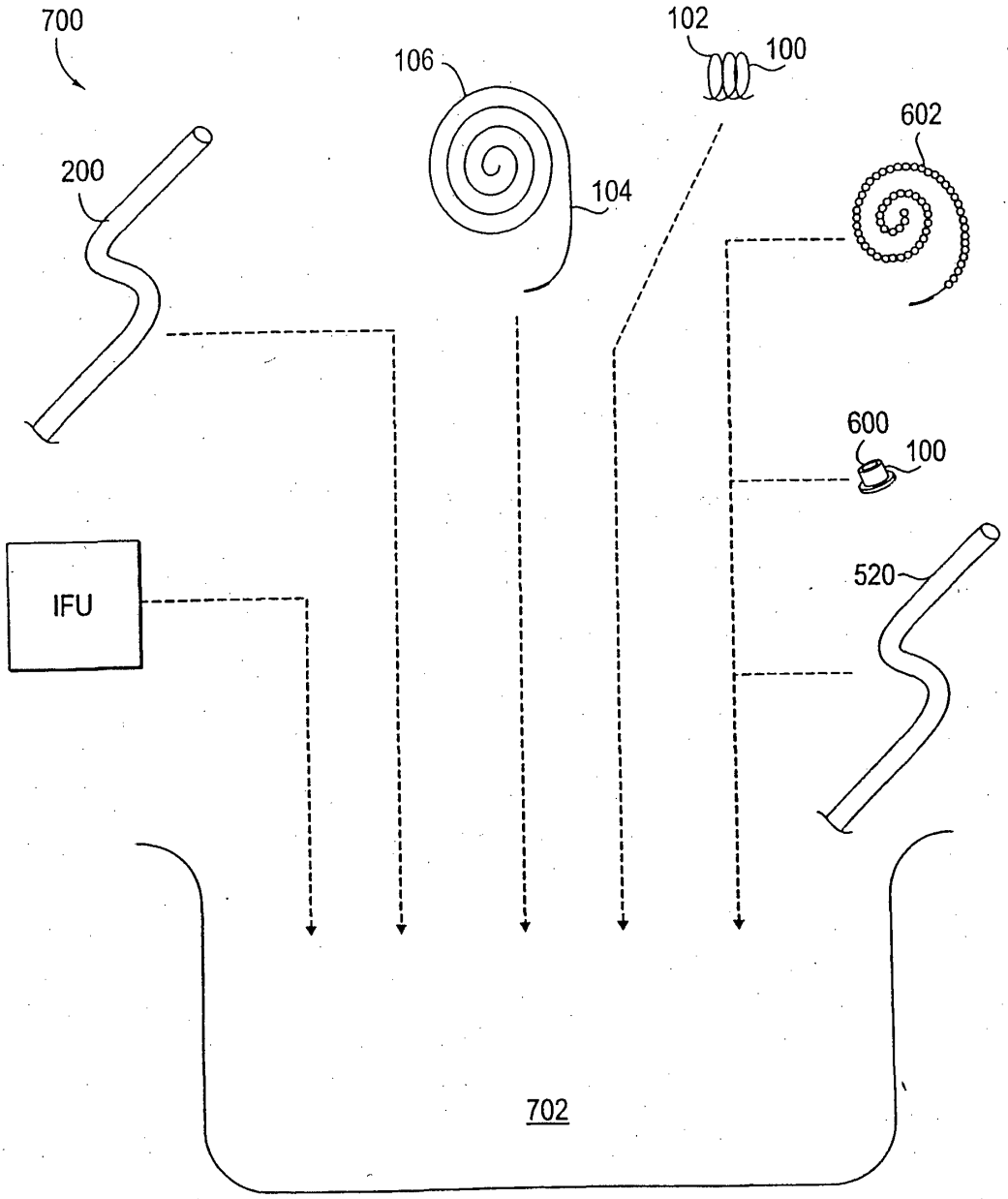



FIG. 25

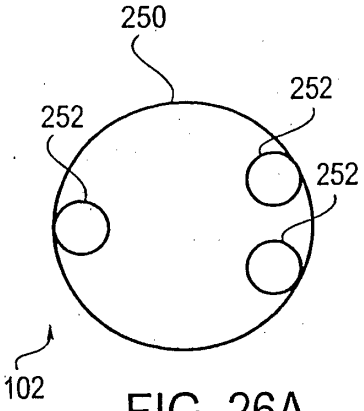



FIG. 26A

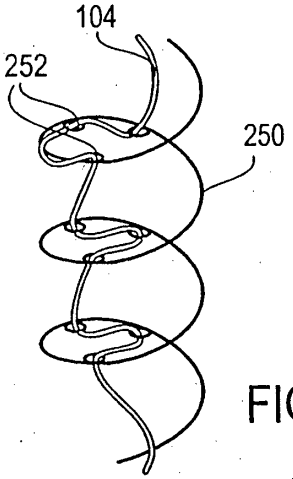



FIG. 26B

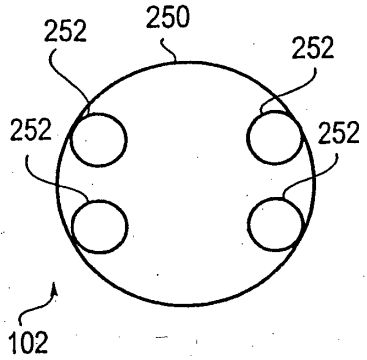



FIG. 27A

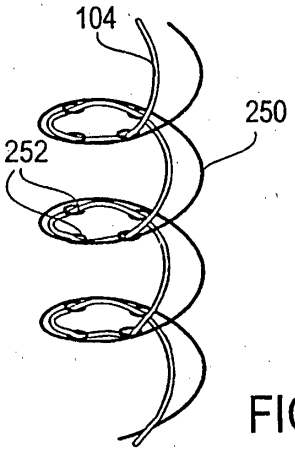



FIG. 27B

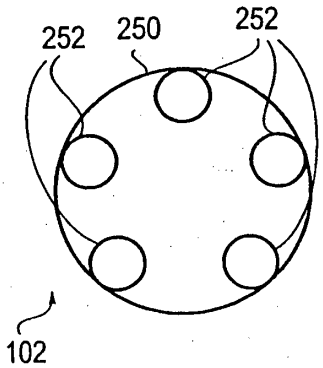



FIG. 28A

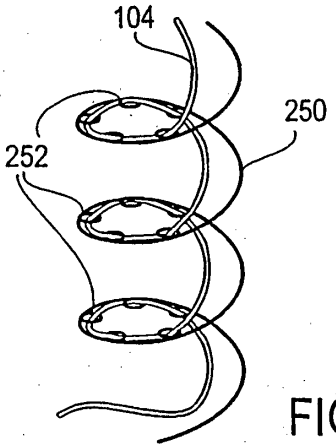



FIG. 28B

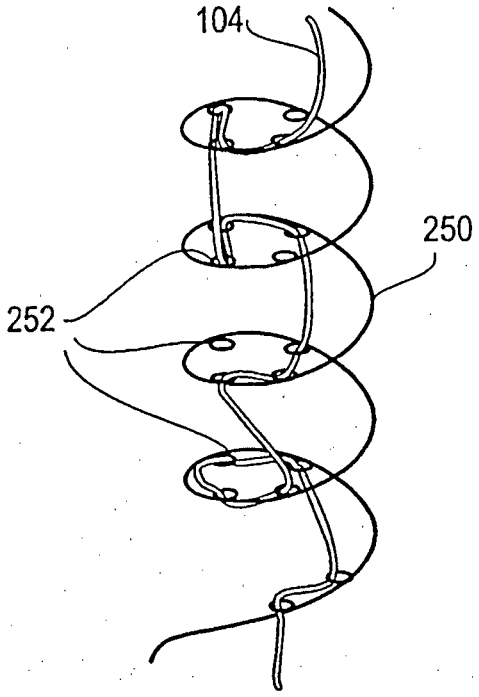



FIG. 29

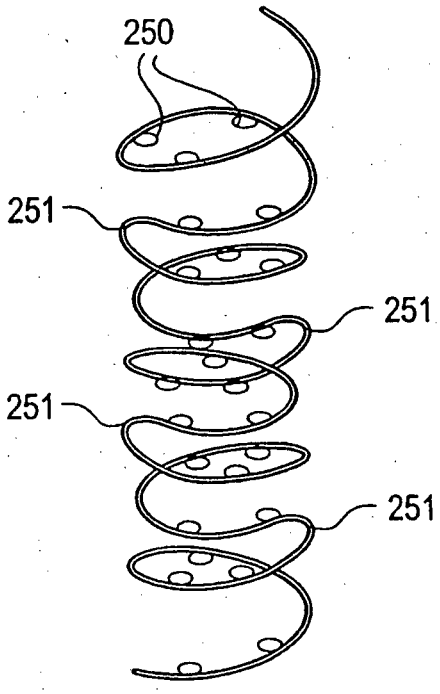



FIG. 30

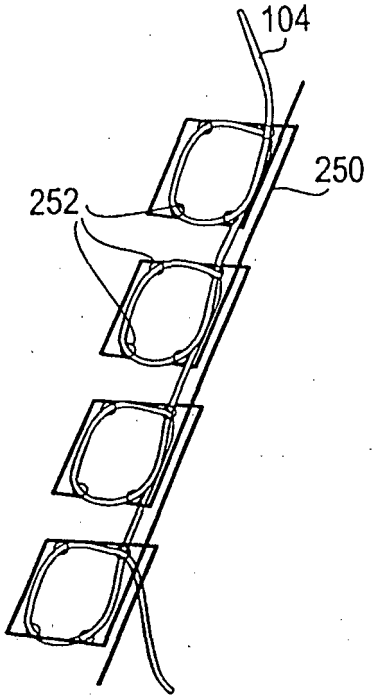



FIG. 31

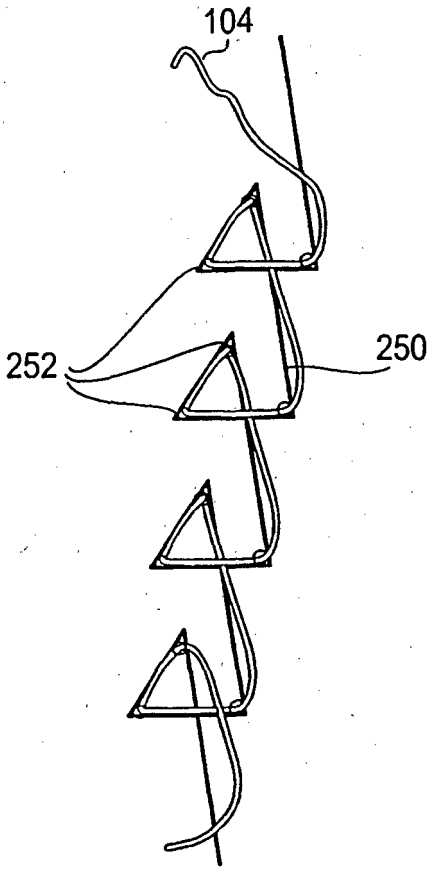



FIG. 32

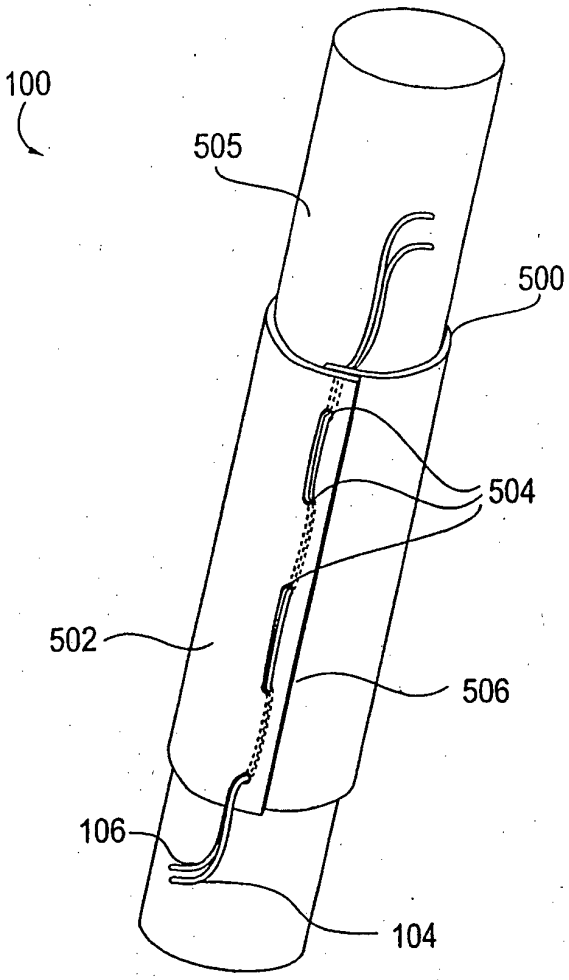



FIG. 33A

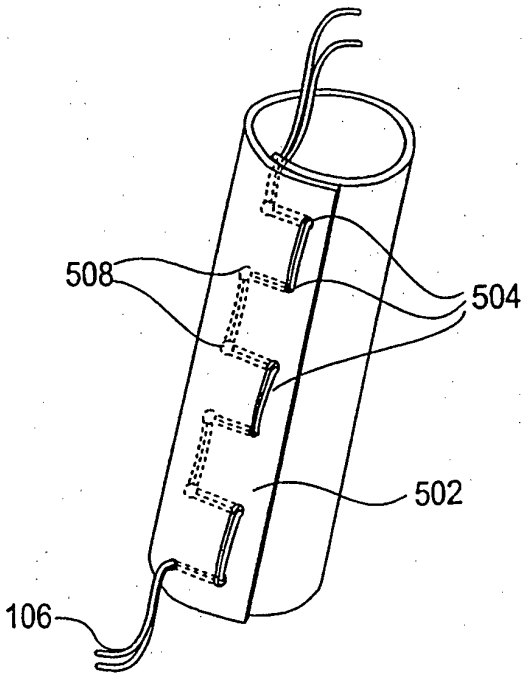



FIG. 33B

## REFERENCES CITED IN THE DESCRIPTION

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